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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,722	01/17/2002	Hiroshi Yanagawa	2001-1921	3316
513	7590	07/01/2004	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,722

Applicant(s)

YANAGAWA ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/284,627.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a Preliminary Amendment, filed January 17, 2002.

Amendments were made to the claims. Specifically, claims 1-21 were cancelled, and new claims 22-30 were added for prosecution.

Claims 22-30 are pending and under consideration in the instant application.

It is noted that Applicant has copied claims from US 6,214,533 for prosecution in the instant application. Specifically, claim 22 and 23 in the instant application are identical to claims 1 and 2 from US 6,214,533. Applicant points to the specification at page 40, lines 10-24, page 12, line 11 to page 14, line 7, page 46 lines 17-23, and page 50, lines 2-3 for support on the instantly present copied claims. Applicant asserts that the prepared mRNA and/or viral genome is naturally a library because it is synthesized or prepared from a library itself.

The Office acknowledges the implicit support for a library for the following reasons: (1) On page 40 (set forth by Applicant as supporting the instant claims), the specification teaches the production of "assigning molecules" from a gene or cDNA library. The plurality of the term "assigning molecules" implicitly means that more than one molecule can be made from the library; (2) the "assigning molecules" set forth in the specification, and which are generically claimed in the parent application (no US Patent 6,361,943), comprise any number of individual specific molecules, which when considered collectively form a library of molecules. As such, the instant claims regarding a library of "assigning molecules" are believed supported implicitly within the instant application.

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Priority

Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/284,627 (now US Patent 6,361,943), filed on October 17, 1997. It is noted that an English translation of the foreign priority document is also present in the parent application.

Information Disclosure Statement

The information disclosure statements filed January 17, 2002 and April 30, 2004 have been considered, and a signed and initialed copy of the form PTO-1449s are attached to this Office Action.

Claim Objections

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the term "library of protein-encoding RNA molecules" does not literally appear in the specification, therefore the claims do not have proper antecedent basis in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4-8 of U.S. Patent No. 6,361,943 (henceforth the '943 patent) in view of Brenner et al. (IDS reference AO; henceforth Brenner).

Claims 2 of the '943 patent is drawn to a generic molecule comprising a nucleic acid portion and a protein portion covalently bound to each other, and wherein the protein portion of the molecule is encoded by the nucleic acid portion of the molecule; these portions are linked by way of the 3'-terminus of the nucleic acid. Although the claims do not explicitly state that the nucleic acid portions of the generic molecules are RNA molecules, claims 6-8 of the '943 patent clearly contemplate that the nucleic acids are RNA molecules. When the nucleic acid portion of the molecule is RNA, it necessarily comprises mRNA because it encodes for a gene (the definition of an mRNA). Thus, the claims of the '943 patent make obvious a generic molecule comprising a protein encoding RNA covalently bonded at its 3'-terminal end to a non-RNA (i.e., the protein) molecule (such as in claims 22 and 30). Claims 6-8 of the '943 patent also contemplate further embodiments of the generic molecule: in claim 6, the molecule further comprises a spacer between the RNA and protein portions, wherein the spacer comprises DNA and polyethylene glycol (such as in instant claims 27 and 28); in claim 7, the molecule further comprises a spacer comprised of double-stranded DNA (such as in claims 23 and 25 of the

instant case); in claim 8, the molecule further comprises a spacer region of double-stranded RNA and either a short chain PNA or short-chained DNA (such as in claims 24, 26 and 29 of the instant invention). Because these claims all depend from the same generic claim, it would be obvious to combine the limitations in any various combinations, said limitations all being contemplated within the broader scope of the generic claim. However, the '943 patent does not specifically claim these generic molecules in the form of a library. However, it is clear that the claims contemplate the generation of more than one such molecule, since the molecules are indicated in a generic sense. Thus, the generation of more than one single specific molecule necessarily suggests the formation of a library, which is interpreted as a collection (i.e., anything more than a single specific entity-in this case a protein-encoding RNA-non-RNA moiety hybrid molecule).

Brenner teaches the benefits of libraries of compounds, which is a standard way to search for lead compounds useful as drugs (see for example the first two paragraphs of page 5381, left side).

It would be obvious for the skilled artisan to make a library of the generically claimed molecules set forth in the claims of the '943 patent because the claims are directed to a generic molecule, which inherently contains many individual species of molecules within the genus. This collective group of these individual species represents a collection of molecules, or a library, and it would have been obvious to the skilled artisan to make any molecule that falls within the genus. The ordinary skilled artisan would have been motivated to generate this library because, as Brenner teaches, screening libraries is a standard method to identify lead compounds for drugs, which are desirable compounds for the treatment of diseases. Absent evidence to the

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contrary, the skilled artisan would have had a reasonable expectation of success when making a library of molecules based upon the generically claimed molecule of the '943 patent, in view of the benefits of libraries taught by Brenner.

Claims 22-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 7-10 of copending Application No. 10/228,070 (henceforth the '070 application; also available as pre-grant publication US 2003/0022230) in view of Brenner et al. (IDS reference AO).

Claims 5 (depending from claim 4, which depends from claims 1-3) of the '070 application is drawn to a generic molecule comprising a nucleic acid portion and a protein portion covalently bound to each other, and wherein the protein portion of the molecule is encoded by the nucleic acid portion of the molecule; these portions are linked by way of the 3'-terminus of the nucleic acid, and the nucleic acid portions of the generic molecules are RNA molecules. When the nucleic acid portion of the molecule is RNA, it necessarily comprises mRNA because it encodes for a gene (the definition of an mRNA). Thus, claim 5 of the '070 patent makes obvious a generic molecule comprising a protein encoding RNA covalently bonded at its 3'-terminal end to a non-RNA (i.e., the protein) molecule (such as in claims 22 and 30). Claims 7-10 of the '070 application also contemplate further embodiments of the generic molecule: in claim 7, the molecule further comprises a spacer between the RNA and protein portions, wherein the spacer comprises DNA and RNA (such as in instant claim 23); claim 8, the molecule further comprises a spacer between the RNA and protein portions, wherein the spacer comprises DNA and polyethylene glycol (such as in instant claims 27 and 28); in claim 9, the

molecule further comprises a spacer comprised of double-stranded DNA (such as in claims 23-25 of the instant case); in claim 10, the molecule further comprises a spacer region of double-stranded RNA and either a short chain PNA or short-chained DNA (such as in claims 24, 26, and 29 of the instant invention). Because these claims all depend from the same generic claim, it would be obvious to combine the limitations in any various combinations, said limitations all being contemplated within the broader scope of the generic claim. However, the '070 application does not specifically claim these generic molecules in the form of a library. However, it is clear that the claims contemplate the generation of more than one such molecule, since the molecules are indicated in a generic sense. Thus, the generation of more than one single specific molecule necessarily suggests the formation of a library, which is interpreted as a collection (i.e., anything more than a single specific entity-in this case a protein-encoding RNA-non-RNA moiety hybrid molecule).

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER